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April 14, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

(Docket No.00D-0084)

Re: Draft Guidance for Industry on Special Protocol Assessment
65 *Federal Register* 6377 (February 9, 2000)

Dear Dockets Management Branch:

Pfizer Inc. submits these comments on the "Draft Guidance for Industry on Special Protocol Assessment" published in the *Federal Register* on February 9, 2000.

1. Clarification is needed regarding the proposal to have an Advisory Committee review clinical protocols. Although one would surmise that such a meeting would be closed, given that the compound would be in the development (i.e., IND) stage and that design features would be proprietary, the recent decision to make Briefing Documents publicly available for unapproved drugs leaves enough uncertainty to warrant addressing this proposal more specifically. Another concern we have about the proposal is that if Advisory Committee agendas are full for several months (due to the need to meet user fee dates on NDAs under review), involving Advisory Committees in clinical protocol assessment may potentially stall development.

2. We understand from the draft guidance that FDA expects to maintain an open dialogue with sponsors regarding protocols submitted for special assessment. As the draft states at lines 68-70: "sufficient time should be allowed to discuss and resolve any issues before the study begins." We agree that it is important for the Agency and the sponsor to have opportunities to discuss issues relating to proposed protocols in a timely manner. To ensure that this can occur, we suggest that FDA clarify that Agency-sponsor discussions regarding special protocol assessments submitted in accordance with this draft guidance may be conducted independently of other CMC issues. Such clarification will avoid a possible conflict with the recent draft guidance, "IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information," which advocates only one multidisciplinary meeting at product milestones (e.g. End of Phase 2, pre-NDA).

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3. We agree with PhRMA's assessment of the disparate timeframes for evaluation of clinical protocols and those for carcinogenicity assessment. Further, the guidance is silent on the procedure for notifying sponsors of an insufficient supportive package. Given that the proposal suggests delaying initiation of carcinogenicity studies by 75 days (30 days for the pre-notification and 45 additional days to receive comments), it would be useful to have an early indication if the supportive package does not contain sufficient information for the CAC to complete its evaluation. Further, it might be useful to outline the roles and responsibilities of the CAC (or refer to the MaPPs which contain this information) as there may be some misperception by the general community that CACs and formal Advisory Committees operate similarly, which is not the case.

4. The draft guidance proposes that an additional 45 days be added every time there is a revision to the protocol. These revisions may either be sponsor-directed or Agency-directed. In the case of minor modifications or Agency-directed revisions, 45 days seems excessive since the Agency is already familiar with the development plan, data and protocol design.

5. In the "Content of a Request" section of the draft guidance (line 144) it is recommended that the sponsor describe the regulatory outcome (e.g., approval of a specific claim) and final labeling that the sponsor believes would be supported by the results of the study. It is premature at this point in development to discuss wording for final labeling. Thus, we suggest that either proposed or anticipated labeling be provided in the request in lieu of final labeling.

6. Line 259 notes that any dispute regarding study design should be resolved prior to initiation of the trial. If so, the timing of the response from FDA on the dispute resolution/feedback needs to be specified; the current timelines for dispute resolution are unacceptable in this instance.

Sincerely,

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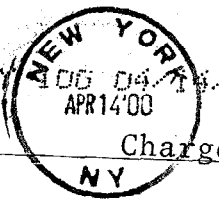

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